

K070772

APR 30 2007

510 (k) Summary

Device description

PressX Zr is a dental press ceramic system that is intended to be used by professional dental technicians to manufacture all-ceramic dental prostheses for the sole use of particular patients.

The PressX Zr system consists of solid glass ceramic (porcelain) pellets, which are intended to be pressed onto zirconium dioxide frameworks at high temperature, and of porcelain powders, which are intended to stain these all-ceramic restorations, individually.

After overpressing, the restoration can be finished either by using the staining- or by using the layering-technique. For staining, the PressX Zr powders (Bodystains + Glaze) which are components of the PressX Zr system have to be applied. For layering, the ZIROX –powders (a product of Wieland Dental + Technik, K051249) have to be used.

PressX Zr can be pressed onto any zirconium dioxide material, which has a coefficient of thermal expansion [CTE _(25-500°C)] of about $10 \times 10^{-6} \text{ K}^{-1}$.

Indications for use

The indications of the all –ceramic restorations, which are fabricated with zirconium dioxide frameworks and PressX Zr are mainly determined by the specifications of the zirconium dioxide framework materials and are fixed by their manufacturers.

Usually, zirconium dioxide frameworks are intended for manufacturing dental crowns and bridges for the anterior and posterior region.

Additionally, PressX Zr can be used to manufacture all-ceramic inlays, onlays, and veneers without zirconium dioxide frameworks.

There is no limitation of the device regarding the patient population, in which commonly known contraindications for all-ceramic restorations, like bruxism, have to be considered by the dentists.

Comparison with the predicate device

PressX Zr equals the predicate device with regard to the intended use, material constituents, application process (overpressing technique), recommended framework material, biocompatibility and chemical solubility.

Compared to the predicate device, PressX Zr has a higher flexural strength according to ISO 6872, and “standard crowns” made of PressX Zr have a significantly higher fracture resistance.

For this reason, PressX Zr is at least as safe, as effective and performs as well or better than the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Gerhard Polzer
Director, Regulatory Affairs
Wieland Dental + Technik GmbH & Co. KG
Schwenninger Strasse 13
D-75179 Pforzheim
GERMANY

APR 30 2007

Re: K070772

Trade/Device Name: PressX Zr
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: March 16, 2007
Received: March 21, 2007

Dear Dr. Polzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu S. Lin', with a stylized flourish at the end.

Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070772

Device Name: PressX Zr

Indications for Use:

PressX Zr is a pressable dental ceramic that can be used by dental technicians to fabricate all-ceramic restorations by pressing-over zirconium dioxide frameworks. The indications of these all-ceramic restorations are defined by the manufacturers of the zirconium dioxide (ZrO₂) framework material, and normally encompass dental crowns and bridges.

The coefficient of thermal expansion [CTE (25 - 500°C)] of these zirconium dioxide (ZrO₂) frameworks has to equal approximately $10 \times 10^{-6} \text{K}^{-1}$

In addition, PressX Zr can be used to manufacture all-ceramic inlays, onlays, and veneers without zirconium dioxide frameworks.

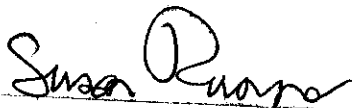
Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Susan Russo
Director of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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(Posted November 13, 2003)